London International Group, Inc.

P.O. Box 8308
Dothan, Alabama 36304

January 26, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 98N-0313: Surgeon's and Patient Examination Gloves; Reclassification.

Dear Madam or Sir:

Our company is a member of HIMA and values the importance of this organization as a representative of the medical device industry and as a liaison with FDA.

Recently we have participated in a HIMA group of medical glove companies drafting comments to the FDA on the proposal to reclassify medical gloves from Class I to Class II devices. HIMA will be sending these comments to FDA this week. These comments by HIMA represent a consensus of the participants and not unanimity of opinion of HIMA's members.

There are many points in the HIMA comments with which we agree, particularly those supporting the need to use consensus standards (like those of ASTM), efforts to present protein limits for gloves in a form based on glove surface area, and the support of reclassification of medical gloves to Class II devices.

We cannot, however, agree with the extreme position taken by HIMA in its comments regarding the safety of gloves powder. As has long been our position, Regent Medical believes that there is a significant body of scientific evidence regarding the contribution of starch powder to postoperative complications and latex allergies.

We have advised the HIMA group drafting the comment letter that we felt compelled to advise FDA of our disagreement with some aspects of the HIMA comments to FDA.

Sincerely,

Bradley L. Pugh
Vice President, Scientific Affairs

BLP:jgs

98N-0313

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